alpha orthopaedics

JUN 18 2012

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. General Information

Date Summary Prepared: May 31, 2012

Submitted by: Alpha Orthopaedics, Inc.
7700 Edgewater Drive, Suite #405
Oakland, CA 94621
Phone: (510) 969-7323
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Contact name: Gina To
Vice President, Regulatory/Quality

2. Name of Device

Trade Name: Alpha Orthopaedics AT2 System
Common Name: Electrosurgical cutting and coagulation device and accessories
Classification: Product code GEI, Class II, CFR §878.4400

3. Legally Marketed Predicate Devices for Claimed Equivalence

- K031046 Thermage ThermaCool TC System: primary predicate device for substantial equivalence claim
- K082956 Alpha Orthopaedics AT2 System: predicate device for substantial equivalence claim

4. Device Description

The AT2 System utilizes monopolar radiofrequency energy for coagulation and to induce tissue changes in dermatologic and general surgical procedures. It consists of a RF generator, cooling module, handpiece, and sterile disposable single-patient use treatment electrodes. It uses accessories including coupling fluid, return pad, coolant canister, and skin marking paper. The AT2 System applies to specific areas of the body radiofrequency energy while cooling the surface of the tissue in contact with the treatment electrode and uses dielectric as the method of applying radiofrequency via the treatment electrode. This submission adds treatment electrodes that have electrode patient contact surface area of 0.25cm^2 and 1.50cm^2.

5. Intended Use

The AT2 System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

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6. Technological Characteristics

The technological characteristics of the AT2 System, including treatment electrodes, are identical to the Thermage ThermaCool TC System, as follows:

Operational principle:	The system delivers RF energy while cooling the surface of the tissue in contact with the treatment electrode
Modes:	Monopolar/Bipolar
Capacitive vs. Inductive:	Capacitive
Operating Frequency:	6 MHz
Treatment Electrodes:	Sterile, disposable, single patient use
Tuning	Tuning function built into RF Generator and automated. Process is software controlled.

7. Substantial Equivalence

The AT2 System with the addition of 0.25cm^2 and 1.50cm^2 treatment electrodes has the same intended use and the same technological characteristics as the legally marketed predicate device cleared under K031046 and K082956.

8. Summary of Performance Testing

Biocompatibility, EMC, safety, and bench tests have been completed.
The technological characteristics demonstrate that the Alpha Orthopaedics AT2 System is as safe, as effective, and performs as well as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 18 2012

Alpha Orthopaedics, Incorporated
% Ms. Gina To
7700 Edgewater Drive
Suite 405
Oakland, California 94621

Re: K120527
Trade/Device Name: Alpha Orthopaedics AT2 System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 31, 2012
Received: June 5, 2012

Dear Ms. To:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120527

Device Name: Alpha Orthopaedics AT2 System

Indications for Use:

The AT2 System is indicated for use in Dermatologic and General Surgical procedures for electrocoagulation and hemostasis.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120527